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JC894 U.S. PTO 08/11/00

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UTILITY PATENT APPLICATION TRANSMITTAL

(Only for new nonprovisional applications under 37 C F R. § 1.53(b))

Attorney Docket No.	1480
First Inventor or Application Identifier	Beck, Robert
Title	Catheter
Express Mail Label No.	EK865250375

JC857 U.S. PTO 09/637529 08/11/00

APPLICATION ELEMENTS

See MPEP chapter 600 concerning utility patent application contents

ADDRESS TO: Assistant Commissioner for Patents, Box Patent Application, Washington, DC 20231

1. [X] * Fee Transmittal Form *(e.g., PTO/SB/17)* *(Submit an original and a duplicate for fee processing)*
2. [X] Specification [Total Pages 11] *(preferred arrangement set forth below)*
   - Descriptive title of the Invention
   - Cross References to Related Applications
   - Statement Regarding Fed sponsored R & D
   - Reference to Microfiche Appendix
   - Background of the Invention
   - Brief Summary of the Invention
   - Brief Description of the Drawings *(if filed)*
   - Detailed Description
   - Claim(s)
   - Abstract of the Disclosure
3. [X] Drawing(s) *(35 U.S.C. 113)* [Total Sheets 8]
4. Oath or Declaration [Total Pages]
   a. [ ] Newly executed (original or copy)
   b. [X] Copy from a prior application (37 C.F.R. § 1.63(d)) *(for continuation/divisional with Box 16 completed)*
      i. [ ] DELETION OF INVENTOR(S) Signed statement attached deleting inventor(s) named in the prior application, see 37 C.F.R. §§ 1.63(d)(2) and 1.33(b).

NOTE FOR ITEMS 1 & 13: IN ORDER TO BE ENTITLED TO PAY SMALL ENTITY FEES, A SMALL ENTITY STATEMENT IS REQUIRED (37 C.F.R. § 1.27), EXCEPT IF ONE FILED IN A PRIOR APPLICATION IS RELIED UPON (37 C.F.R. § 1.28)

5. [ ] Microfiche Computer Program *(Appendix)*
6. Nucleotide and/or Amino Acid Sequence Submission *(if applicable, all necessary)*
   a. [ ] Computer Readable Copy
   b. [ ] Paper Copy (identical to computer copy)
   c. [ ] Statement verifying identity of above copies

ACCOMPANYING APPLICATION PARTS

7. [ ] Assignment Papers (cover sheet & document(s))
8. [ ] 37 C.F.R.§3.73(b) Statement *(when there is an assignee)* [ ] Power of Attorney
9. [ ] English Translation Document *(if applicable)*
10. [ ] Information Disclosure Statement (IDS)/PTO-1449 [ ] Copies of IDS Citations
11. [X] Preliminary Amendment
12. [X] Return Receipt Postcard (MPEP 503) *(Should be specifically itemized)*
13. [ ] * Small Entity Statement(s) *(PTO/SB/09-12)* [X] Statement filed in prior application, Status still proper and desired
14. [ ] Certified Copy of Priority Document(s) *(if foreign priority is claimed)*
15. [X] Other: Check in the amount of $345

16. **If a CONTINUING APPLICATION,** *check appropriate box, and supply the requisite information below and in a preliminary amendment:*

[ ] Continuation [X] Divisional [ ] Continuation-in-part (CIP) of prior application No 08 / 862,277

Prior application information: Examiner Mendez, M Group / Art Unit: 3736

For CONTINUATION or DIVISIONAL APPS only: The entire disclosure of the prior application, from which an oath or declaration is supplied under Box 4b, is considered a part of the disclosure of the accompanying continuation or divisional application and is hereby incorporated by reference. The incorporation can only be relied upon when a portion has been inadvertently omitted from the submitted application parts.

17. CORRESPONDENCE ADDRESS

[ ] *Customer Number or Bar Code Label* *(Insert Customer No. or Attach bar code label here)* or [X] *Correspondence address below*

Name	Robert C. Beck				
	Beck & Tysver				
Address	1011 First Street South				
	Suite 440				
City	Hopkins	State	MN	Zip Code	55343
Country	USA	Telephone	952-933-3412	Fax	952-933-3049

Name (Print/Type)	Robert C. Beck	Registration No. (Attorney/Agent)	28,184
Signature	Robert C Beck	Date	8/11/00

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The PTO did not receive the following listed item(s): paper Declaration

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	**Robert C. Beck**	Examiner:	**(Mendez, M.)**
Serial No.:	**TBD**	Group Art Unit:	**(3734)**
Filing Date:	**May 23, 1997**	Docket No.:	**1480**
Title	**Catheter**		

Date of Deposit: 8/11/00
I hereby certify that this paper is being deposited in the United States Postal Service, as first class mail, in an envelope addressed to: Assistant Commissioner for Patents, Washington, DC 20231

Signature: Robert C Beck
Printed Name: Robert C Beck

Preliminary Amendment

Assistant Commissioner for Patents
Washington, DC 20231

This application is a continuation (divisional) of parent case 08/862,277 filed 05/23/1997. This preliminary amendment corrects typographical and numbering errors and introduces incorporated material from the provisional application entered into the parent application.

Figures 2 and 3 from the provisional have been relabeled as figures 5 and 6 respectively. Corresponding numbering changes have been made and no new matter has been introduced. New drawing are submitted herewith.

AMENDMENTS

Please amend the specification as follows:

On page 2, line 12, after "remove" insert -- **this**--.

On page 3, line 2, delete "catcher" and insert thereof

--**catheter** --.

On page 3, line 25, insert

--**Fig. 5 is a schematic diagram of an alternate embodiment of the catheter;**

Fig. 6 is a schematic diagram of an alternate embodiment of the catheter. --.

On page 2, line 12, after "remove" insert -- **this**--.

On page 4, line 13, delete "21" and insert thereof

--**2** --.

On page 4, line 17, delete "21" and insert thereof

--**2** --.

On page 5, line 6 delete "24" and insert thereof

--**42** --.

On page 6, line 5, delete "87".

On page 7, line 10, delete "if" and insert thereof

--**If** --.

On page 7, line 13, delete "colluded" and insert thereof

--**connected** --.

On page 7, line 14, insert

-- Turning to Fig5, there is shown a distal 11 end portion of an illustrative first embodiment of the thrombectomy catheter 10. The outer diameter of the thrombectomy catheter 10 is defined in this embodiment by the sheath 24 which also forms and defines one wall of a throat 36 with respect to a flow control body 16. The sheath 24 also defines a central axis 37. The high pressure supply lumen 18 delivers fluid to a slit 40 which discharges fluid in a generally radial direction with respect to the central axis 37. In

operation, the slit 40 will have dimensions defining a slit orifice area smaller than the cross-sectional dimension of the interior of the high pressure supply lumen 18. In the figure the slit 40 directs the jet away from the central axis at ninety degrees but other angles are contemplated within the scope of the disclosure. A slight step 42 may be formed proximate the flow control body 16. The height of the step helps to turn the sheet of fluid 44 which emerges from the slit 40. As the fluid emerges, it entrains fluid on both sides of the jet. Since the amount of fluid which can be entrained on the inner side next to the flow control body 16 is limited, the jet turns and follows the contour of the body 16, thus turning through approximately ninety degrees in the illustrative example into the annular throat 36 formed between the sheath 24 and the body 16. Both lesser and greater degrees of turning are contemplated. Ninety degrees of turning is desirable because it presents more fluid entrainment area to engage and eject thrombus.

This embodiment of the device also shows a guide wire 26 which may be used to position the thrombectomy catheter 10 within a body vessel. For use in coronary applications, it is important that the guide wire be small, and the discharge sheath is shown with an opening 46 which permits the thrombectomy device 10 to be delivered over the guidewire 26. It should also be noted, that the position of the aperture 46 is sufficiently proximal of the distal end of the sheath 24 to permit retraction of the guide wire 26 fully into the discharge lumen 20.

Fig. 6 shows an illustrative alternate second embodiment or design for the thrombectomy catheter 10. In this version of the device the nozzle slit 33 is formed as an annular ring at the periphery of the outer sheath 24. Once again the jet is issued radially at an angle with respect to the central axis 37. In this version secondary jets 41 may be formed between the supply lumen and the discharge lumen to assist in removal of debris. In this version the high pressure supply lumen 18 delivers fluid to the plenum

39 which distributes the fluid to the annular ring jet 33. The control body 17 forms a throat 35 which may be large enough to permit passage of a guide wire through the throat area. Although the slits in each embodiment differ in detail each preferably has a characteristic length which is larger than the corresponding width. However due to manufacturing considerations rows of round holes may be substituted for the slit shown in the figures. It should also be noted that the complex body contours can be approximated by more easily manufactured conical sections --.

In the Claims

Kindly cancel the claims 1-10 in the application as originally filed and substitute these claims which are numbered from the highest number in the previous prosecution.

18. A catheter system comprising:

an ablation catheter having a catheter body said catheter body having a distal tip said distal tip having a first maximal diameter;

a sheath having a internal diameter substantially equal to said first diameter of said ablation catheter;

said ablation catheter located within said sheath and adapted for motion with respect to said sheath;

whereby said ablation catheter can be moved independently of said sheath.

19. A catheter system according to claim 18 wherein said internal diameter of said sheath is slightly larger than said first diameter of said ablation catheter.

20. A catheter system according to claim 18 wherein said internal diameter of said

sheath is substantially equal to said first diameter of said ablation catheter.

21. A catheter comprising:

a catheter body having a proximal end and having a distal end;

said catheter body defining an axis;

said distal end having an approximately circular cross section;

a high pressure lumen in said catheter body terminating near the distal end;

an annular aperture encircling the distal end of the catheter body, connecting the high pressure lumen with the exterior surface of said catheter body;

said annular aperture defining a first aperture direction for the emerging flow that lies between approximate zero degrees and one hundred and eighty degrees

said annular aperture cooperating with said catheter body to direct an annular sheet of fluid emerging from said aperture along said catheter body such that said distal end is substantially encircled with fluid from said aperture.

22. The catheter of claim 21 wherein said annular aperture is formed by a set of individual holes.

23. The catheter of claim 22 wherein said set of individual holes are substantially equidistant around the periphery of said distal end of said catheter.

24. The catheter of claim 23 wherein said holes are approximately round in cross section.

25. The catheter of claim 23 wherein said holes are approximately rectangular in cross

section.

26. The catheter of claim 21 further including :

a control body surface located immediate adjacent said aperture, providing a barrier located proximate said aperture, for limiting fluid entrainment from the location of said control body, near the aperture by the jet emerging from the aperture, whereby said jet is deflected by a pressure difference across said barrier.

27. A catheter comprising:

a catheter body having a proximal end and having a distal end;

a high pressure lumen located in said catheter body;

a series of apertures communicating with said high pressure lumen;

said series of aperture substantially completely encircling said distal end;

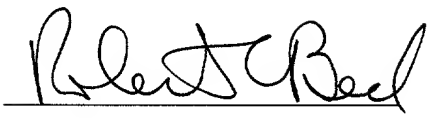
a control body formed in said catheter body adjacent said series of apertures blocking fluid entrainment from the area proximal of said apertures by a jet emerging from said apertures.

28. The catheter device of claim 26 wherein a tangent drawn to said control body surface at the location of the aperture is parallel to the aperture direction.

29. The catheter device of claim 26 wherein a tangent drawn to said control body surface at the location of the aperture forms an included angle with the aperture direction that is greater than zero degrees and less than ninety degrees.

ROBERT C. BECK
By his attorneys:

Date: 8-10-00



Robert C. Beck
Registration No. 28,184
Beck & Tysver, P.L.L.P.
1011 First Street South, #440
Hopkins, MN 55343
Telephone: (612) 933-3412
Fax: (612) 933-3049

CATHETER

Cross Reference to Related Applications

The present application is a continuation in part of provisional patent application 60/018,333 filed 05/24/96 entitled "Thrombectomy Catheter". This provisional application is incorporated herein in its entirety and the benefit of its filing date is claimed for all that it teaches.

1. Field of the Invention

The invention relates generally to a catheter, and more particularly to a device that utilizes the energy in a pressurized fluid to interact with and remove occlusive material from vessels or lumens in the body.

2. Background of the Invention

Catheters which are used to remove occlusive material from lumens within the body are well known. Occlusive material such as plaque, atheroma, and emboli vary in their mechanical properties and various energy sources have been proposed to break up occlusive material. These proposals include the use of high energy fluid jets or the circulation of an abrasive slurry within the vessel. The use of mechanical impellers and/or blades has been proposed and experimental work has been performed with a "rotoblader" device. Laser light energy and either ultrasonic or acoustic energy have been proposed to breakdown occlusive material. The use of radio frequency electromagnetic energy has been proposed as well.

For example fluid pressure thrombectomy systems are known from United States Patent No. 4,690,672 to Veltrup among others. In the Veltrup device, a reward-facing jet entrains thrombus and blood from the patient, and ejects these into a secondary discharge lumen which removes both thrombus and blood from the body. Linear or straight line fluid jets which

represent the current technology, are relatively inefficient in removing thrombus because of the jet geometry.

Impeller based cutting devices are known from United States Patent No. 4,729,763 among others. In this device the mechanically rotated blade interacts directly with the occlusive material.

Ultrasonic based devices are known from United States Patent No. 5,368,557. In this device the ultrasonic energy is used to break up the occlusive material and a fluid is supplied to cool the ultrasonic tip. In general there are two functions which must be supplied. First sufficient energy must be available to disrupt the occlusive material. Secondly loose material must be efficiently removed from the body. Most particulate occlusive material is thrombogenic and failure to remove material can result in a distal embolism.

SUMMARY OF THE INVENTION

In contrast to the devices of the prior art, the present invention teaches the use of a deflected jet alone or in conjunction with a complimentary energy source to break up and transport occlusive material out of the body. The deflected jet is a substantially annular sheet of fluid which becomes attached to a barrier and which is then deflected through an angle. This deflected jet entrains ambient fluid on its outer surface and the combined stream is deflected through an angle of about ninety degrees in most embodiments. This deflected jet presents a large and energetic surface to entrain and emulsify occlusive material. In operation the jet emerges from a generally annular nozzle or slit and attaches itself to a shoulder of a flow control body. As the jet emerges from the nozzle it

spreads over the contour of the shoulder which gives the jet a greater working area. The jet ultimately enters a throat formed in the catcher which provides good pressure recovery for the jet improving overall efficiency.

In some versions, the catheter may be delivered over a guide wire or through a guide sheath. The construction and geometry of the device permits integration with other energy sources. In these alternate embodiments the deflected jet acts a pump to emulsify and preferentially remove particulate occlusive material. Examples of disclosed energy sources include mechanical impellers, ultrasonic probes, radio frequency probes, and laser fiber systems.

BRIEF DESCRIPTION OF THE DRAWING

The drawings show illustrative embodiments of the catheter. Various modifications to these designs may be made without departing from the scope of the invention. Elements which carry identical reference numerals are equivalent structures.

Fig. 1 is a system level diagram, showing a simple version of the catheter system;

Fig. 2 is a schematic diagram of the distal end of the catheter;

Fig. 3 is a schematic diagram of an alternate embodiment of the catheter;

Fig. 4 is a schematic diagram of an alternate embodiment of the catheter.

Detailed Description

Turning to Fig. 1, the catheter assembly 10 is coupled to an angiographic fluid injector 12. The catheter assembly 10 has a distal end 11 and a proximal end 13. The proximal end includes fittings for a high pressure supply lumen 18 and a lower pressure discharge lumen 20 and a guide wire lumen 22. In the figure the high pressure injector 12 supplies saline from a saline supply at a user selected delivery rate which generates a corresponding pressure sufficient to induce the required flow. Typically, an over-pressure switch is present on the injector 12 to shut the injector off if the high pressure supply line pressure exceeds a pre-set value. In use, the distal end 11 of the catheter assembly 10 interacts with the thrombus or other occlusive material and the energetic saline fluid jet entrains both blood and thrombus from the patient, which are discharged through the lower pressure discharge lumen 20 to a collection vessel 21. In the preferred use, the catheter 10 is delivered by the guide wire 26 to an occluded site in the vasculature. The injector 12 is then activated and the occlusive material is extracted by the deflected jet into the collection vessel 21.

Fig. 2, shows the distal 11 end portion of an illustrative embodiment of the catheter assembly 10 in cross section. The outer diameter of the catheter assembly 10 is defined by the sheath 24. The interior lumen of this sheath 24 forms and defines one wall 35 of a throat 36 formed between the wall 35 and the outer diameter of the flow control body 16. The sheath 24 also defines a central axis 37 for the distal portion 11 of the assembly. The high pressure supply tubing 19 has a lumen 18 which is used to deliver fluid to a slit 40. The slit 40 discharges fluid in a generally radial direction with respect to the central axis 37. In operation, the slit 40

will have dimensions defining an orifice area smaller than the cross-sectional dimension of the interior of the high pressure supply lumen 18. In the figure the slit 40 directs the jet away from the central axis at ninety degrees but other angles are contemplated within the scope of the disclosure. A small land area 42 may be formed on the flow control body 16. This land area 24 helps to turn the sheet of fluid 44 which emerges from the slit 40. As the fluid emerges, it entrains fluid on both sides of the jet. Since the amount of fluid which can be entrained on the inner side next to the flow control body 16 is limited, the jet turns and follows the contour of the body 16, thus turning through approximately ninety degrees in the illustrative example into the annular throat 36 formed between the sheath 24 and the body 16. Both lesser and greater degrees of turning are contemplated at least between 45 and 270 degrees. Ninety degrees of turning is desirable because it presents more fluid entrainment area to engage and eject thrombus. The non-symmetrical jet is highly turbulent and has many eddies. As a consequence the average velocity in the outer surface of the jet is higher than the average flow over the attachment wall 17 of the flow control body 16. Therefore the jet velocity is higher than a conventional jet at the same distance.

This embodiment of the device also shows a guide wire 26 which may be used to position the sheath 24 within a body vessel. For use in coronary applications, it is important that the guide wire be small, and the sheath 24 is shown with an opening 46 which permits the sheath 24 to be delivered over the guide wire 26. It should also be noted, that the position of the aperture 46 is sufficiently proximal of the distal end of the sheath 24 to permit retraction of the guide wire 26 fully into the discharge lumen 20.

As seen in the figure there is a strut 41 which anchors the cap 19 into the flow control body 16. This strut 41 may extend beyond the cap 19 toward the open distal end of the sheath 24. If appropriately formed this portion of the strut may serve as a fixed guide wire and extend as shown by dotted line ~~87~~ in the figure. Thus the flow body 16 may have a guide wire element or the sheath 24 may be advanced over a guide wire 26. As seen in the figure the strut can extend toward the proximal end of the catheter and serve as a fixed guide wire 87.

In the embodiment shown in Fig. 2 it is possible to move the flow control body 16 with respect to the sheath. When a small (3F) flow body is used, the sheath and flow body 16 may be advanced sequentially. The high pressure tubing 19 may be made of hypo tubing or more preferably polyimide tubing. When metal hypo tubing is used the flow body and tubing have the mechanical properties of a guide wire and may be used instead of a guide wire to position the flow body. If polyimide tubing is used the injector can be used to provide low pressure fluid to stiffen the tubing 19 permitting it to be used as a guide wire as well. It should also be noted that the cap 19 may be positioned off center to provide a flow body which advances and turns as it is activated outside the sheath 24. When viewed under imaging equipment this version of the device is steerable under physician control.

Fig. 3 shows an illustrative alternate second embodiment or design for the catheter assembly 10. In this version of the device an additional energy source is provided. For example an air motor 50 is coupled by a flexible shaft 52 to a distal impeller 54. In operation the impeller is rotated inducting thrombus or other occlusive material into the sheath 24.

The masticated material accumulates near the flow control body 16 and the deflected jet 60 entrains this material and ejects it from the device as indicated by stream 62. In this fashion a mechanical blade or impeller can supplement the action of the deflected jet to treat patients with more organized occlusive material.

Fig. 4 shows a remote energy source 70. Several different sources are represented generically by block 70. Specifically included are sources for laser light energy, ultrasonic acoustic energy, and radio frequency electromagnetic energy. In the case of ultrasonic energy and radio frequency energy the probe section may be metal. If the energy source is laser light the probe 72 may be an optical fiber with a lens or other distribution optic at the distal tip of the probe 72. In general the probe which extends distal of the flow control body 16 is colluded to the energy source 70 through a suitable conduit 74.

WHAT IS CLAIMED:

1. A catheter comprising:

a first high pressure supply lumen;

a second low pressure discharge lumen;

said low pressure discharge lumen defining a central axis;

said high pressure supply lumen having a proximal end and having a distal end;

a slit communicating with said high pressure lumen proximate said distal end, said slit directing a jet of fluid in a direction away from said central axis;

a control body positioned proximal of said slit to turn said sheet jet through an angle with respect to said central axis;

a sheath surrounding said body defining a throat for providing pressure recovery for said jet.

2. The device of claim 1, further including an aperture located proximal of said distal end for receiving a guide wire.

3. A thrombectomy catheter comprising:

a discharge lumen;

a fluid supply lumen;

said supply lumen connected to a nozzle;

whereby said nozzle generates a jet of fluid;

a control body located proximate said nozzle;

whereby said fluid jet attaches to and follows said control body, generating a fluid flow;

a throat communicating with said discharge lumen for directing said fluid flow out of said discharge lumen.

4. A catheter for removing occlusive material from a patient comprising:

a fluid supply lumen terminating in a nozzle said nozzle forming a fluid jet;

a control body located proximate said jet for limiting entrainment on one side of said jet;

whereby said jet becomes attached to said body and follows the contour of said body;

a discharge lumen located proximate said body to receive fluid from said jet.

5. A catheter having a distal end and having a proximal end, said catheter comprising:

a high pressure lumen;

a low pressure lumen;

a deflected jet proximate said distal end for collecting occlusive material and for directing said occlusive material into said low pressure lumen.

6. The device of claim 5 further including a impeller located distal of said deflected jet.

7. The device of claim 5 further including a blade located distal of said deflected jet.

8. The device of claim 5 further including a sonic probe located distal of said deflected jet.

9. The device of claim 5 further including a radio frequency energy probe located distal of said deflected jet.

10. The device of claim 5 further including an ultrasonic energy probe located distal of said deflected jet.

ABSTRACT

A hydraulic catheter which uses a deflected jet to entrain thrombus into a discharge lumen. Multiple energy sources including ultra sonic mechanical and optical energy may be used with the deflected jet energy.

Fig. 1

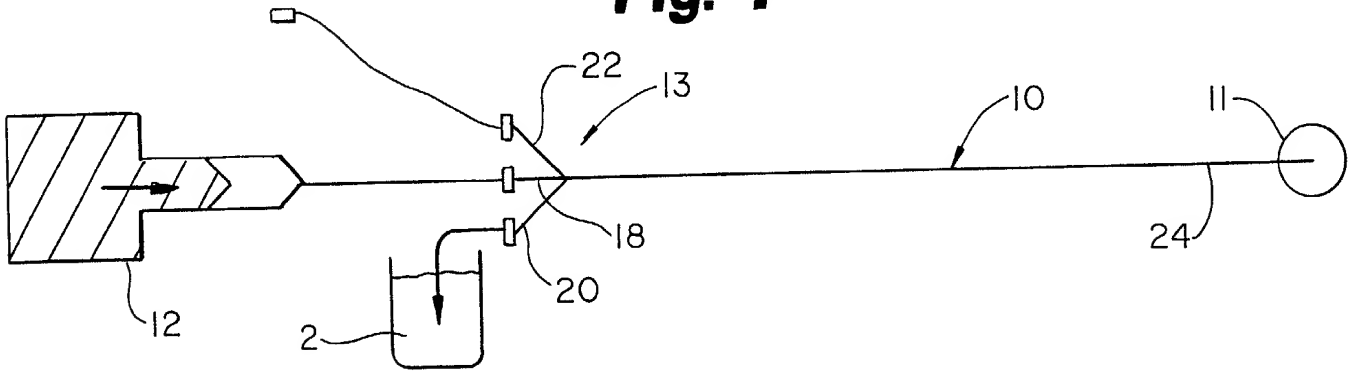


Fig. 2

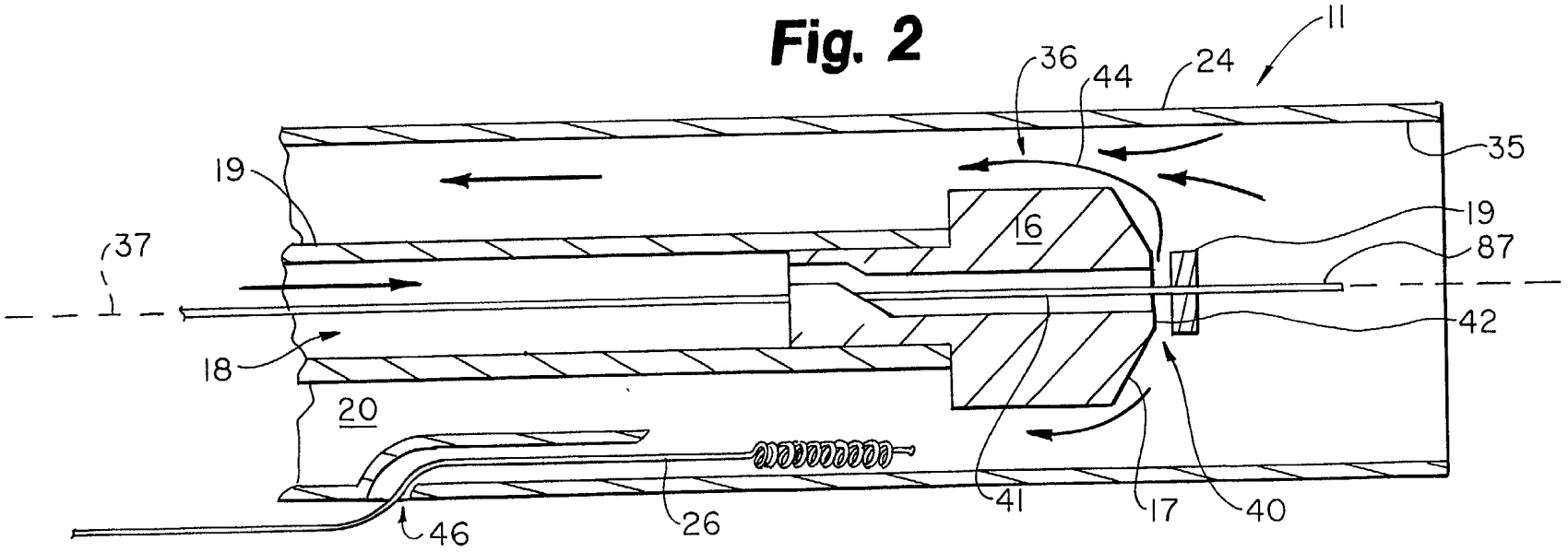


Fig. 3

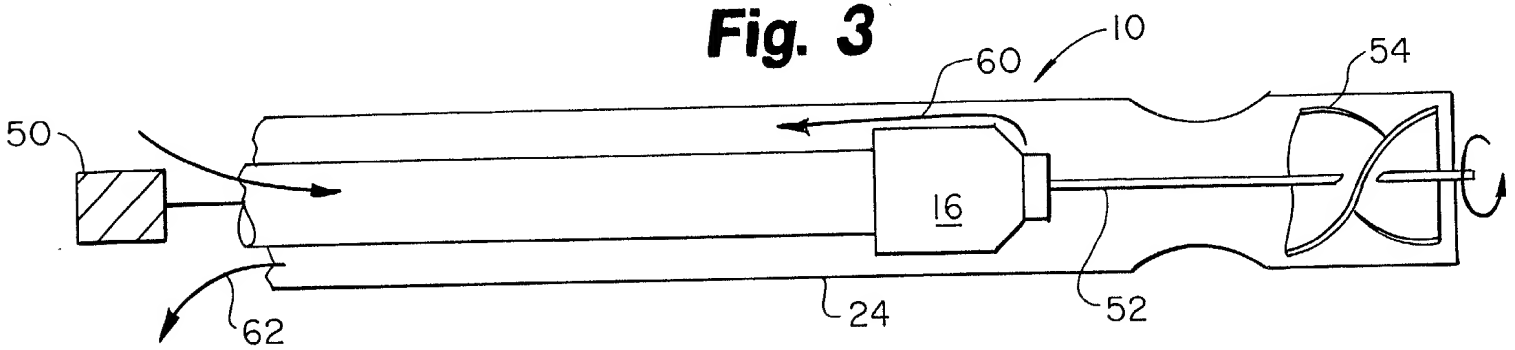


Fig. 4

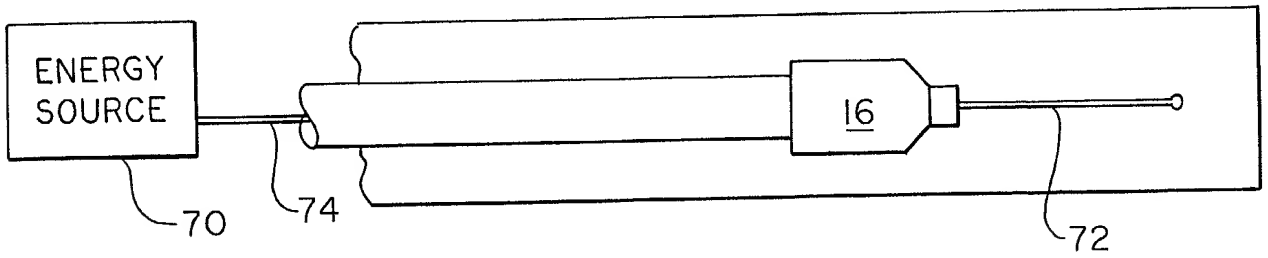


Fig. 5

Fig. 6

Please type a plus sign (+) inside this box → ☐

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DECLARATION — Utility or Design Patent Application

I hereby claim the benefit under Title 35, United States Code §120 of any United States application(s), or §365(c) of any PCT international application designating the United States of America, listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States or PCT International application in the manner provided by the first paragraph of Title 35, United States Code §112, I acknowledge the duty to disclose information which is material to patentability as defined in Title 37, Code of Federal Regulations §1 56 which became available between the filing date of the prior application and the national or PCT international filing date of this application

U.S. Parent Application Number	PCT Parent Number	Parent Filing Date (MM/DD/YYYY)	Parent Patent Number (if applicable)
provisional Applin 60/018,~~000~~ 333		5/24/96	60/018,~~333~~ 333 5/24/96

☐ Additional U S or PCT international application numbers are listed on a supplemental priority data sheet PTO/SB/02B attached hereto

As a named inventor, I hereby appoint the following registered practitioner(s) to prosecute this application and to transact all business in the Patent and Trademark Office connected therewith ☐ Customer Number [ ] → *Place Customer Number Bar Code Label here*
OR
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Name	Registration Number	Name	Registration Number

☐ Additional registered practitioner(s) named on supplemental Registered Practitioner Information sheet PTO/SB/02C attached hereto

Direct all correspondence to ☐ Customer Number or Bar Code Label [ ] *OR* ☒ Correspondence address below

Name	Robert Beck						
Address	2256 Hendon Ave						
Address							
City	St Paul			**State**	MN	**ZIP**	55108
Country	USA	**Telephone**	612 644 2816			**Fax**	

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true, and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon

Name of Sole or First Inventor: ☐ A petition has been filed for this unsigned inventor

Given Name (first and middle [if any])	Family Name or Surname
Robert C Beck	

Inventor's Signature	Robert C Beck							**Date**	5/23/97
Residence: City	St Paul	**State**	MN	**Country**	USA			**Citizenship**	USA
Post Office Address	2256 Hendon Ave								
Post Office Address	S								
City	St Paul	**State**	MN	**ZIP**	55108	**Country**	USA		

☐ Additional inventors are being named on the ____supplemental Additional Inventor(s) sheet(s) PTO/SB/02A attached hereto